Appendix B



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

41405d

Food and Drug Administration Washington DC 20204

JUN 20 2001

WARNING LETTER ONPLDS 20-01

BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Gerry Morrison President Morico Foods, Inc. 2102 Kotter Ave. Evansville, Indiana 47715

Dear Mr. Morrison:

The Food and Drug Administration (FDA) has reviewed the label for Carbolite. Our review reveals that this label causes the above product to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (21 CFR).

This product is misbranded because the label bears the nutrient content claim "Carbolite" that is not authorized by regulation or the Act (Section 403(r)(1)(A)). FDA has defined the nutrient content claim "Lite" by regulation. This definition does not extend to lite in carbohydrate.

The product is further misbranded because the label bears the claim "Zero Carbohydrate" and the statement "Maltitol has been omitted from the total carbohydrate content...." Maltitol is a carbohydrate and must be included in the value declared for "Total Carbohydrate" within, as well as, outside of nutrition labeling (Sections 403(a), 403(q) and 21 CFR 101.9(c)(6).

The above violations are not meant to be an all inclusive list of deficiencies on your labels. It is your responsibility to ensure that all of your products are labeled in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these deviations and prevent their future recurrence. Failure to make prompt corrections could result in regulatory action without further notice. Possible actions include seizure and/or injunction.

As some additional information we question whether "2 pieces (7g)" is an accurate serving size for this product and request your explanation of the basis for this serving size.

Page 2 - Mr. Gerry Morrison

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken or plan to take to correct the noted violations. Copies of revised labels for the product should be submitted. If corrective actions eannot be completed within 15 working days, state the reason for delay and the time within which corrections will be completed.

You should direct your written reply to me at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, Office of Nutritional Products, Labeling and Dietary Supplements (HFS-810), 200 C Street, S.W., Washington, D.C. 20204.

Sincerely yours,

ohn B. Foret

Director

Division of Compliance and Enforcement Office of Nutritional Products, Labeling and Dietary Supplements

Center for Food Safety and Applied Nutrition

Appendix C



UNITED STATES PATENT AND TRADEMARK OFFICE

TESS was last updated on Sat Dec 14 04:10:48 EST 2002

PTO HOME TRADEMARK TESS HOME NEW USER STRUCTURED PREE FORM BROWN DICT Воттом FIRST DOC PREV DOC NEXT DOC LAST DOC CURR LIST

Please logout when you are done to release system resources allocated for you.

Start | List At:

OR Jump to record:

Record 9 out of 16

Check Status

TARR contains current status, correspondence address and attorney of record for this mark. Use the "Back" button of the Internet Browser to return to TESS)



Word Mark 0 SUGAR CARBS

Goods and Services

IC 030. US 046. G & S: soft serve ice cream, bake mixes, namely cookie mixes, waffle mixes, cake mixes and pizza crust mixes, bread mixes, shake mixes, cappuccino drink mixes, mousses, namely, flavored, sweetened gelatin; cheesecakes, chocolate bars, and candy. FIRST USE: 20011200. FIRST USE IN COMMERCE: 20011200

Mark

Drawing

(5) WORDS, LETTERS, AND/OR NUMBERS IN STYLIZED FORM

Code

Serial

76421257

Number

Filing Date June 14, 2002

Owner

(APPLICANT) Carbolite Foods, Inc. CORPORATION DELAWARE 1325 Newton

Avenue Evansville INDIANA 47715

Attorney of Record

Daniel J. Lueders

Type of Mark

TRADEMARK

Register

PRINCIPAL

Live/Dead

Indicator LIVE

PTO HOME TRADEMARK TESS HOME NEW USER STRUCTURED PRECEDEM BROWNLOWS THE HELP CONTROL CURR LIST RECEIVED PREV DOC NEXT DOC LAST DOC